IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Donoho *et al.*	Group Art Unit: 1646	
Application No.:	09/775,181	Examiner: R. Li	
Filed:	02/01/2001		
Title: Novel Human Membrane Proteins and Polynucleotides Encoding the Same		Atty. Docket No. LEX-0129-USA	

REQUEST FOR CONTINUED EXAMINATION UNDER 37 C.F.R. § 1.114
AMENDMENT AND RESPONSE

Commissioner for Patents
Washington, D.C. 20231

Sir:

The Applicants acknowledge the receipt of the Advisory Action mailed on August 14, 2002 (Paper No. 12), which has been carefully reviewed and studied. The Applicants respectfully request continued examination of application Serial No: 09/775,181 and submit the following amendment and respectfully request reconsideration of the application in view of this amendment and remarks. A Petition for an Extension of Time of two months to and including January 17, 2003 and authorization to deduct the fee as required under 37 C.F.R. § 1.17(a)(1) from Applicants' representatives Deposit Account are included. The response is thus timely filed. Applicants believe no fees in addition to the fee for the extension of time are due in connection with this response. However, the Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 50-0892.

AMENDMENTS

A clean copy of the pending and amended claims are attached as Exhibit A. A marked up copy of the pending claims are attached as Exhibit B.

Please amend Claim 2 so that the text of the amended claim reads as follows, such that highly

stringent hybridization conditions are defined verbatim as in the specification

2. (Thrice Amended) An isolated nucleic acid molecule comprising a nucleotide sequence that:

Amended) An isolated nucleic acid molecule comprising a nucleotide sequence that:

(a) encodes the amino acid sequence shown in SEQ ID NO:2; and

(b) hybridizes under highly stringent conditions to filter-bound DNA in 0.5 M $NaHPO_4$, 7% sodium dodecyl sulfate (SDS), 1 mM EDTA at 65°C, and washing in 0.1xSSC/0.1% SDS at 68°C

RESPONSE

I. Status of the Claims

Claim 2 has been amended. Claims 1-8 are therefore presently pending in the case. For the convenience of the Examiner, a clean copy of the pending claims is attached hereto as **Exhibit A**. In compliance with 37 C.F.R. § 1.121(c)(1)(ii), a marked up copy of the original claims is attached hereto as **Exhibit B**.

II. Support for the Amended Claims

Claim 2 has been amended to further clarify the claim, and to recite verbatim the highly stringent conditions in the specification. Amendment of Claim 2 finds support throughout the specification as originally filed, with particular support being found at page 7, lines 21-27.

As the amendment to claim 2 is fully supported by the specification and claims as originally filed, they do not constitute new matter. Entry, therefore, is respectfully requested.

III. Rejection of Claims Under 35 U.S.C. § 101

The Action persists in rejecting claims 1-8 under 35 U.S.C. § 101, allegedly because the claimed invention lacks support by either a specific and substantial asserted utility or a well established utility. Applicants respectfully continue to traverse.

Applicants have presented evidence of multiple utilities in previous responses dated April 3,

2002 and July 12, 2002, for the present invention, a novel G-protein coupled receptor. G-protein coupled receptors are well established drug targets.

In addition, Applicants now present further clear and convincing evidence that those of skill in the art would readily recognize the utility the present invention. The Actions in the present case have repeatedly argued that without knowing biological function of the claimed molecule, one of skill in the art would not know what to do with the claimed invention. Applicants respectfully disagree as the current invention is a G-protein coupled receptor, a commonly known drug target. Additionally, a knockout mouse has been made in which the mouse gene homologous to that represented by SEQ ID NOS: 1 and 2 was disrupted by homologous recombination. These knockout mice were subject to a medical work-up using an integrated suite of medical diagnostic procedures designed to assess the function of the major organ systems in a mammalian subject. Disruption of the mouse gene of the present invention and the protein it encodes resulted in an increase in mean cholesterol and triglyceride levels in the blood of male animals in which this gene activity had been disrupted. This clearly provides evidence that the nucleic acid and protein of the present invention have a biological function and that antagonists directed at the molecule of the present invention be used to lower blood cholesterol and triglyceride levels, which have been shown to directly lower the risk of heart attacks. Thus clearly the molecules of the present invention have a real world utility. Applicant encloses for the Examiner's information a recently published in Nature Reviews Drug Discovery, that describes the value and utility of the knockout mouse in identifying drug targets to the pharmaceutical industry (Exhibit C).

Those of skill in the art would clearly recognize the utility of the present invention as well as be enabled to make and use the present invention without undue experimentation. Thus, the present invention clearly has credible and well established utility. In light of the evidence presented above and in previous responses, Applicants respectfully submit that the present invention is in full compliance with the provisions of 35 U.S.C. § 101, and respectfully request that the rejection be withdrawn.

IV. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

The Action rejects claims 1-8 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the claimed invention, as the invention allegedly is not supported by a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse.

Applicants submit that as claims 1-8 have been shown to have a specific, substantial, credible and well established utility (see above) and given the above and related disclosures, the wealth of published art, as well as issued U.S. Patents on the utility and use of GPCRs and combined the disclosure of the present invention, those of skill in the art would clearly recognize the present invention as a valuable drug target and would know how to make and use the present invention without undue experimentation. Applicants therefore respectfully request that the rejection of claims 1-8 under 35 U.S.C. § 112, first paragraph, be withdrawn.

V. Rejection of Claim 2 Under 35 U.S.C. § 112, Second Paragraph

The Advisory Action rejects Claim 2 as allegedly indefinite for use of the term highly stringent. While Applicants in no way agree with this rejection and believe that the original Claim 2 was definite, in order to more rapidly progress the case to allowance, Applicants have amended Claim 2 to include *verbatim* the highly stringent hybridization conditions from the specification. Applicants respectfully submit that this rejection has thus been avoided by Applicant's amendment of Claim 2 and respectfully request withdrawal of the pending rejection of Claim 2 under 35 U.S.C. § 112, second paragraph.

VI. Conclusion

The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Li have any questions or comments, or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

January 16, 2003
Date

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